Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-06 ISO-00 OES-05 /018 R

66612
DRAFTED BY: DHEW/FDA/JRWEINROTH, M.D.
APPROVED BY: OES/SCI/BMP: MBEAUBIEN
DHEW/OIH/MACODDING
AF/S:RJDOLS (INFO)
---------- 112959
R 202234Z MAY 75
FM SECSTATE WASHDC
TO AMEMBASSY PRETORIA

UNCLAS STATE 117962

E.O. 11652: N/A
TAGS: OGEN, ETRD, TBIO, SF

SUBJECT: FDA ADVISORY - DEFECTIVE THERAPEUTIC ELECTRONIC PRODUCT.

1. FDA ADVISES THAT ALL UNITS OF THE MEVATRON 8 LINAC LINEAR ACCELERATORS, SERIAL NOS. 1021 THROUGH 1047, MANUFACTURED BY APPLIED RADIATION CORPORATION, 2404 N. MAIN STREET, WALNUT CREEK, CALIFORNIA 94596, DURING 1968 THROUGH 1969 HAVE A DEFECT WHICH RELATES TO THE SAFETY OF USE BY REASON OF EXCESSIVE RADIATION EXPOSURE.

2. THE MANUFACTURER NOTIFIED FDA THAT TWO PATIENTS HAD RECEIVED EXCESSIVE RADIATION EXPOSURE BECAUSE THE OPERATOR RESET THE MACHINE AFTER A PRESET DOSE RATE INTERLOCK SHUT OFF SINCE THE CONSOLE INCORRECTLY REGISTERED A LOWER DOSE RATE. INVESTIGATION REVEALED THAT A FUSE IN THE HIGH VOLTAGE SUPPLY TO THE ELECTRON DOSE CHAMBER WAS OPEN WHICH ALLOWED A SMALL CURRENT TO PASS AND THEREFORE INCORRECTLY REGISTERED A LOW DOSE READING WHEN USED IN THE ELECTRON THERAPY MODE.

3. MODIFICATION OF THE UNITS ARE REQUIRED, CONSISTING OF REPLACING THE FUSE HOLDER WITH A NON-INDICATING TYPE, AND ADDING A HIGH VOLTAGE INTERLOCK CIRCUIT.
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4. POST IS REQUESTED TO DETERMINE IF FOREIGN CONSIGNEE IS
FAMILIAR WITH THE NATURE OF THE PROBLEM AND THE CORRECTIVE ACTION
TO BE TAKEN. ANY QUESTIONS CONCERNING THIS PROBLEM SHOULD BE
REFERRED TO THE MANUFACTURER.

5. FOREIGN CONSIGNEE, AS FOLLOWS:

NATIONAL HOSPITAL - BLOEMFONTEIN, ORANGE FREE STATE PROVINCE,
POSBUS/P.O. BOX 517, BLOEMFONTEIN, UNION OF SOUTH AFRICA.
INGERSOLL

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Capture Date: 01 JAN 1994
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